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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,207

06/30/2006

Michael A. Levy

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03/24/2008

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

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SUITE 800

WASHINGTON, DC 20005

EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

03/24/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,207	<b>Applicant(s)</b> LEVY, MICHAEL A.	
	<b>Examiner</b> BINTA M. ROBINSON	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/3/06</u> . | 6) <input type="checkbox"/> Other: ____.  |

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15, 33-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, lines 3-4, and everywhere else throughout the claims, the phrase "providing a saponified solution comprising a pyridine-2,3-dicarboxylic acid ester and a base" is unclear because a saponified solution already contains an ester that has been hydrolysed from an ester to a carboxylate salt. Here, the ester exists as the ester rather than the salt. This phrase also contradicts the phrase in claim 16, lines 4-5, wherein the phrase reads "saponifying said solution by adding a base, thereby forming a saponified solution comprising a pyridine-2,3 -dicarboxylic acid salt".

B. Claims 33-49 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: are the steps of converting the intermediate pyridine-2,3-dicarboxylic acid to the 2-(2-imidazolin-3-yl)nicotinic acids, esters, and salts.

C. In claim 9, line 2, page 14, and everywhere else throughout claim 10, the phrase "an amount necessary to change the color of said saponified solution from a darker color to a lighter color" is unclear because this amount is not specified at the claim. Additionally, it is unclear, because by definition – an amount of oxidizing agent effective to remove impurities will be the amount necessary to change the color of the

saponification mixture from a darker color to a lighter color. See page 9, lines 30-31 and page 10, line 1 of the specification.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauwenberg et. al.

Cauwenberg et. al. teaches the process for recovering a pyridine-2,3-dicarboxylic acid from a process stream in the preparation process of the pyridine,2-3,dicarboxylic acid in which process the process stream is subjected to nanofiltration, the feed pressure is higher than atmospheric pressure, and the pyridine-2,3-dicarboxylic acid-containing concentrate is utilized. The process claimed in the prior art is one wherein in the pyridine-2, 3-dicarboxylic acid is purified and recovered to 83%. At column 2 of the patent, it is stated that one method for preparation of pyridine, 2, 3-dicarboxylic acids is through hydrolysis of the corresponding esters and that this method is well known. This is the saponification reaction. See column 2, lines 7-8. The claim does not specifically, recite that the pyridine-2,3-dicarboxylic acid achieved done by saponification and acidification, however, the claim does not exclude these steps because it uses the language "in the preparation process of the pyridine-2,3-dicarboxylic acid" – the actual process of preparation is not specified, but is generic and hence inclusive.

The difference between the prior art process and the instantly claimed process is the teaching of a generic, unspecified preparation process of preparing the pyridine 2,3-dicarboxylic acid, with specified reaction conditions in which PH and feed pressure are specified, and the purification step which is nanofiltration (See claim 1 at column 4, lines 20-30) versus the teaching a process in which the pyridine 2,3-dicarboxylic acid is produced by saponification, and purification is obtained via an oxidizing agent and the reaction conditions such as temperature, and pressure are not specified. It would have been obvious to one of ordinary skill in the art to replace one purification method with another. The specification cites only one example on page 12, as enabling of its broad claim that all pyridine 2, 3 dicarboxylic acids can be purified utilizing an oxidizing agent. However, the pyridine 2,3 dicarboxylic acid in Example 1 is only referred to as a "crude diester" and the actual structure of the pyridine 2,3 – dicarboxylic acid is not specified.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being obvious over Van Der Puy et. al.

Van der Puy et. al. teaches that that dimethyl 1, 6-dihydro-6-oxo-pyridine-2,4-dicarboxylate was converted into the diacid by the addition of aqueous 5% NaOH and that this product was further oxidized with elemental fluorine to further increase the yield of the final product of pyridinones. See page 4389, lines 1, and 16-18 and the "experimental section" of page 4391 and page 4392. Specific reaction conditions of mmols of reactant used, temperature, and solvent are specified in the prior art, however, the claims do not exclude these reaction conditions because the term "comprising" which is open-ended language is used. The prior art also specifies that

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the diacids are in the form of pyridinones, yet the instant claims does not limit the pyridine 2, 3, dicarboxylic acids to exclude pyridinones because the specific actual structure of the pyridine, 2, 3-dicarboxylic acids is not specified, but just claimed generically.

The difference between the prior art process and the instantly claimed process is the teaching of a pyridine, 2, 3-dicarboxylate versus a pyridine 2, 3 -dicarboxylic acid ester to which a base is added. Saponification is defined as the hydrolysis of an ester in a base, the product of which is a carboxylate salt. The free acid is generated when the solution is acidified. Here, the step of the saponification reaction is missing where the ester is converted to a carboxylate salt. Here the carboxylate salt is provided and is further acidified to the corresponding carboxylic acid. It would have been obvious to one of ordinary skill in the art to modify the prior art process using the routine organic reaction of saponification to hydroxylize the pyridine 2, 3-dicarboxylic acid ester to the corresponding carboxylate rather than to introduce the carboxylate into the reaction system without that step. Accordingly, the process is deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed process over those of the prior art process.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant describes at page 12, line 6 of the specification that a crude diester is saponified- however, the applicant does not specify the structure of the crude diester. As can be seen for example, in claim 48, a diester could be substituted or unsubstituted, however, the applicant has not stated which diester is being saponified and hence which diacid is being produced.

Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. “The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims”, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. In the present case, the important factors leading to a conclusion of undue experimentation are the absence of any

working example where the structures of the diester used and the diacid produced – are specified – and the absence of any working example in which 2-(2-imidazolin-2-yl)nicotinic acids are produced and the absence of any working examples wherein oxidizing agents other than H<sub>2</sub>O<sub>2</sub> are used.

c) There is no working example where the specific structure of the diester used in the reaction or the specific diacid produced are specified. See example I on page 12, line 9. Additionally, the claims are drawn to all oxidizing agents, yet the singular example in the specification only uses H<sub>2</sub>O<sub>2</sub>. There is no evidence that all other oxidizing agents work to produce a diacid with a 98.9% purity. Hence, applicants must show that all other oxidizing agents can be used to produce diacids to a great degree of purity, accordingly.

g) The state of the art is that it is not predictable whether all other oxidizing agents will behave similarly in removing in-situ impurities from a saponified solution of pyridine-2,3-dicarboxylic acid ester. Thus, in the absence of experimentation, one cannot predict if a particular oxidizing agent will purify a saponified solution of pyridine-2,3-dicarboxylic acid using the instant process steps. h) The breadth of the claims includes all oxidizing agents and in claims 1-14, 16-30, 33-47, any and all pyridine -2,3-dicarboxylic esters. Thus, the scope is broad.



MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Janet Andres can be reached on 571-272-0867.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703305-3592, and (703305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

/Binta M Robinson/

/JANET L ANDRES/

Examiner, Art Unit 1625

Supervisory Patent Examiner, Art Unit 1625

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